REMARKS

I. Status of the Application

Claims 1-17 are presently pending in the application. Claims 1-17 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1-4 and 6-8 stand rejected under 35 U.S.C. §102(b) as being anticipated by Freeman, U.S. Patent No. 3,919,773. Claims 5 and 9-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Polson et al., U.S. Patent No. 5,487,897. Applicants respectfully request reconsideration of the pending claims in view of the following amendments and remarks.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, claim 5 has been amended to place it in proper Markush group format.

The amendments presented herein add no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance. The present Amendment After Final Rejection is being filed within 2 months of the mailing date of the Final Office Action. Accordingly, Applicants request issuance of an advisory action.

II. Claims 1-17 do not Recite New Matter

At page 2 of the instant Office Action, claims 1-17 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action states that there is no teaching or reasonable suggestions in the originally filed disclosure that demonstrate the core being "substantially nonporous." The Office Action states that, although

the surface is disclosed, the specification remains silent as to the core of the device. The Office Action concludes that the evidence pointed out by Applicants does not constitute the original disclosure, and, therefore, any amendments based on those later additions constitute new matter. Applicants respectfully traverse this rejection.

The first paragraph of 35 U.S.C. § 112 requires that the specification provide a written description of the claimed invention:

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The purpose of the written description requirement is to ensure that the specification conveys to those skilled in the art that the applicants possessed the claimed subject matter as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). Applicants submit that the claimed invention is described with sufficient particularity to demonstrate that Applicants had possession of the claimed invention, namely, a biodegradable implant having a porous surface and a substantially nonporous core.

Applicants' originally filed specification includes a description of how to make the claimed implants, and following Applicants' teachings provided in the original specification results in the production of an implant having a porous surface and a substantially nonporous core. Applicants' originally filed specification provides the following teachings: at Example 1, Applicants teach how to compression mold a 10:90 TMC/PLA copolymer sample, and how to immerse the sample in a plasticizer solution for 30 seconds, followed by a 30 minute incubation on a metal net to ensure the diffusion of plasticizer into the copolymer prior to implantation; at Example 3, Applicants teach how to immerse a compression molded PLLA/PGA/TMC

copolymer sample in plasticizer for 30 seconds, followed by a 20 minute diffusion step to allow the plasticizer to diffuse into the copolymer; at Example 4, Applicants provide a protocol for compression pressing a variety of polymer granulates, making polymer strips and immersing polymer strips in a plasticizer for 40 seconds, followed by a 30 minute incubation in a metal net to ensure diffusion of plasticizer into the polymer. Each of these methods produces the claimed implant having a porous surface.

Although the instant specification does not expressly state the physical characteristics of the core, the protocols provided by Applicants ***necessarily*** result in the formation of a polymer having a substantially nonporous core and one of ordinary skill in the art would recognize this fact. Because it is the exit of the plasticizer from the claimed implant that causes pore formation, and because Applicants' specification teaches soaking the implant for only 30 or 40 seconds, one of skill in the art of implants would instantly appreciate that the plasticizer would only be present in the implant at the surface, and that this is implicit in Applicants' disclosure. The minimal contact time of the implant with the plasticizer simply would not be sufficient for allowing the plasticizer to diffuse beyond the surface of the implant. In fact, Applicants teach, "when the plasticizer diffuses from the implant, a ***porous layer is formed on the outer surfaces*** of the implant" (paragraph [0017], emphasis added). Thus, one of skill in the art would recognize that the instant specification provides adequate written description of an implant having a porous surface and a substantially nonporous core.

Further, in Applicants' Amendment and Response mailed December 15, 2005, Applicants provided physical evidence (at Tab C) that implants made according to the methods disclosed in the originally filed specification do indeed have a porous surface and a substantially nonporous core. If one of skill in the art was to make the claimed implant guided by Applicants'

specification, an implant having a porous surface and a substantially nonporous core would be achieved. Simply because Applicants' specification does not *ipsis verbis* state that the claimed implants have a substantially nonporous core does not mean that recitation of this claim limitation represents new matter. It is well settled case law that one need not include the exact claim language into the specification to meet the written description requirement. Indeed, the nonporous core is an inherent physical characteristic and a necessary result of implants made by one of skill in the art guided by the teachings of Applicants' specification.

In view of the above, Applicants respectfully request that the rejection of claims 1-17 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement be reconsidered and withdrawn.

II. Claims 1-17 Are Novel and Nonobvious over Freeman et al.

At page 3 of the instant Office Action, claims 1-4 and 6-8 stand rejected under 35 U.S.C. §102(b) as being anticipated by Freeman, U.S. Patent No. 3,919,773. The Office Action states that the resulting product is an implant with a porous surface and a non-porous surface. The Office Action further states that the means by which the final product is achieved is a specific process comprising the dissolution of "plasticizers," and that the claim is a product claim where the process is not given patentable weight. Applicants respectfully traverse this rejection.

Applicants' claimed invention is directed in part to a ***biodegradable*** implant that is ***flexible and rigid*** prior to insertion into an organ system, in which the bending resistance of the implant prior to the insertion of the implant into the organ system is substantially lower than after its insertion into the organ system, and has a porous surface and a substantially nonporous core, as well as methods to produce such an implant.

The Freeman reference neither teaches nor suggests Applicants' claimed invention. Freeman is directed to an implant including a ***moldable***, ***non-biodegradable*** matrix, not a biodegradable implant that is flexible and rigid prior to insertion. The moldable matrix of Freeman is easily shapeable. Freeman teaches, "[s]ince the material is moldable, it easily fills and conforms to the shape of a tooth socket" (column 4, lines 25-26). Thus, the implants of Freeman do not provide the physical characteristics of a flexible and rigid implant. In contrast, Applicants' claimed implant maintains sufficient rigidity prior to insertion to provide structural integrity, as well as the flexibility to enable it to be shaped to fit a tissue structure in a very precise manner such that a good fit may be achieved upon implantation.

The Office Action states that, regarding the limitations drawn to a plasticizer, it is the position of the Examiner that such limitations do not impart patentability on the claims. The Office Action states that it is the position of the Examiner that such limitations are essentially product by process limitations within the claim. Applicants disagree. While it is true that implantation of the claimed implant alters its physical characteristics, Applicants respectfully submit that the claimed plasticizer imparts ***unique physical characteristics*** to the claimed implant ***prior to implantation*** that cannot be ignored. Prior to implantation, Applicants' claimed implant is flexible and rigid. In contrast, the implants of Freeman are moldable, not flexible and rigid.

Further, both before and after implantation, the physical properties of Applicants' claimed implants differ markedly from those taught by the Freeman reference. Applicants' claimed implants are ***biodegradable*** implants. In contrast, the implants taught by the Freeman reference are ***not biodegradable***. Although the implants of Freeman are *biocompatible*, nowhere does Freeman teach or suggest the desirability of using a *biodegradable* implant. In fact,

Freeman provides many examples of the ***long-term stability*** of their implants after implantation. For example, Freeman teaches that their implants "form the basis for a crown or other suitable dental restoration" (column 3, lines 10-11); that the implant "maintains the normal oral geometry intact during the healing period" and that the "exposed implant material may then be removed or shaped to receive a crown or other suitable restoration *at some later date*" (column 4, lines 49-52, emphasis added); and that their implants may be used "to replace missing bone" (column 7, lines 7-9). Thus, the implants of Freeman are not biodegradable.

For at least these reasons, the Freeman reference fails to teach or suggest each and every element of Applicants' claimed invention. Accordingly, Applicants request that the rejections of claims 1-4 and 6-8 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

III. Claims 5 and 9-17 are Nonobvious over Freeman in view of Polson et al.

At page 4 of the instant Office Action, claims 5 and 9-17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Polson et al., U.S. Patent No. 5,487,897. The Office Action admits that Freeman et al. is silent to the inclusion of active agents that aid in implantation and bone/tissue growth. The Office Action states that it would have been obvious to include the solvents of Polson et al. into the implant of Freeman et al. in order to improve the solubility of active agents aiding in the healing process. The Office Action concludes that one of ordinary skill in the art would have been motivated to combine the teachings as such with an expected result of properly solubilized implant capable of improving the healing process. Applicants respectfully traverse this rejection. The combination of Freeman and Polson et al. fails to teach or suggest each and every element of the claimed invention.

Polson et el. fails to teach or suggest the claimed implant or methods of making the claimed implant. Polson et al. is directed to an implant comprising an outer sac with a ***liquid component*** contained within (column 2, lines 14-15). Such an arrangement would not create a ***rigid*** implant, as required by the instant claims. In fact, Polson et al. teaches that, "[u]nlike a solid implant, the implant precursor is easy to manipulate and may be ***shaped and molded*** within the defect site as it solidifies. Advantageously, the moldability of the implant precursor allows it to ***conform to irregularities, crevices, cracks, holes, and the like***, in the tissue defect site" (column 5, lines 2-7, emphasis added). Thus, both Freeman and Polson et al. fail to teach or suggest a ***rigid*** implant, as claimed by Applicants.

Polson et el. also fails to disclose implants or methods to manufacture implants having a nonporous core, as required by the claimed implants. Instead, Polson et el. teaches a solid implant having a microporous matrix (column 2, lines 9-10). Thus, the core of Polson et al. contains pores. For at least these reasons, Polson et al. fails to teach or suggest the claimed invention.

Furthermore, Freeman and Polson et al. cannot be combined to arrive at the claimed invention with a reasonable expectation of success. The combination of Freeman and Polson et al. would result in the formation of a material that would be ***unsuitable for use as an implant***. Although the Office Action asserts that it would have been obvious to include the solvents of Polson et al. into the materials of Freeman in order to provide a ***more stable*** implant formulation, this is not so. The implants of Freeman are ***thermoset*** (column 3, lines 31-35). Thus, Freeman's implants have the property of being permanently hard and rigid when heated or cured. The Freeman reference teaches that their implants are polymerized *in situ* (column 2, lines 23-25). Thus, their implants are ***cured after implantation in the body***. Adding a solvent such as NMP to

the material of Freeman prior to curing (i.e., prior to implantation) would interfere with the ability of the implant to properly cure. Specifically, the NMP of Polson et al. would dissolve and/or wash away monomeric components present in the implant material of Freeman prior to polymerization, thus preventing at least some of the monomers from participating in polymerization. This would cause the implant material to be unstable and would render it unsuitable for use as an implant. Accordingly, such an implant would not be appropriate to use as an anchor for a dental implant or to replace bone, which Freeman teaches are desired functions for their implants. Therefore, the combination of these references fails to produce a stable implant, let alone Applicants' claimed implant.

For at least these reasons, the combination of Freeman and Polson et al. fails to render the claimed invention obvious. Accordingly, Applicants request that the rejections of claims 5 and 9-17 under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Polson et al. be reconsidered and withdrawn.

IV. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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